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| **Form** |
| **Declaration by the Responsible Person for foreign manufacturers** |
| **Identification number:** | ZL000\_00\_038 |
| **Version:** | 2.1 |
| **Valid from:** | 29.06.2023 |

# Part A: Production site1

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|  **Annex number**2: …… |
| **Activity**[ ]  Manufacture of active substance Name of active substance: ……or[ ]  (partial) Manufacture of finished product Manufacturing step *(e.g. blending, mixing, tabletting, etc. or "all")*: …… |
| **Name and address of production site**3:Name ……Street ……Postcode / town …… |
| 1 *A separate form must be completed for each site.*2 *This reference, which is defined by the signatory, identifies the document and must be mentioned in the* form *Manufacturer information HMV4.*3 *Please state the exact name and address of the site, including building numbers (if applicable).* |

# Part B: Authorisation to which this declaration refers

This declaration applies to the following authorisations:

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| --- | --- | --- | --- |
| **Name of the medicinal product** | **Dosage** | **Dosage form** | **Authorisation no. (NN’NNN.XX)** |
| …… | …… | …… | …… |
| …… | …… | …… | …… |
| …… | …… | …… | …… |
| …… | …… | …… | …… |
| …… | …… | …… | …… |

# Part C: Basis of Declaration of GMP Compliance

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| [ ]  | Risk assessment enclosed *(Only possible for veterinary medicinal products)* |
| [ ]  | On-site audit of the manufacturer completed by authorisation holderDate of audit4: …… |
| [ ]  | On-site audit of the manufacturer completed by external auditors, e.g. contractor on behalf of the authorisation holderDate of audit4: …… |
| 4 *Justification should be provided if the date of the last audit was more than 3 years ago* |

## Additional information enclosed5

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| 1. The following documents must be enclosed: |
| [ ]  | GMP certificate(s)issued by Swissmedic, EEA authorities, MRA partners or other recognised authorities6 and covering manufacture according to Part A with no restriction. If a GMP certificate from a recognised authority6 exists, this must be submitted. The date of the inspection may not be more than 3 years ago.The document must be available in an official language, in English or in a translation into one of these languages. |
| 2. Or if no such GMP certificate exists |
| [ ]  | Inspection report or equivalent document5issued by Swissmedic, EEA authorities, MRA partners or other recognised authorities6 and covering manufacture according to Part A with no restriction. If a GMP certificate from a recognised authority6 exists this must be submitted. The date of the inspection may not be more than 3 years ago.The document must be available in an official language, in English or in a translation into one of these languages. |
| 3. Or if no such document exists: (not an option for manufacturers of ready-to-use medicinal products from a country whose GMP control system is considered by Switzerland to be equivalent) |
| [ ]  | [ ]  Audit report of the manufacturer on site enclosed7 (only mandatory if no GMP certificate/inspection report that was issued by Swissmedic, EEA authorities, MRA partners or other recognised authorities exists) |
| [ ] List of inspections carried out by foreign authorities in the past 5 years(incl. name of foreign authority, date of inspection, date of completion of inspection and outcome (compliant, non-compliant)). (only mandatory if an audit report was submitted) |
| 4. The following document(s) must **also** be submitted for manufacturers from a country whose GMP control system is not considered by Switzerland to be equivalent: |
| [ ]  | GMP certificate(s)issued by local authorities and covering manufacture according to Part A with no restriction. The document must be available in an official Swiss language, in English or in a translation into one of these languages. If the local authority is Swissmedic or another recognised authority6, please tick the box under point 1. |
| 5. Other relevant information:  |
| [ ]  | Other relevant information: …… |
| 5 See guidance document *Guidance document GMP compliance by foreign manufacturers*6 According to guidance document *Guidance document GMP compliance by foreign manufacturers* and the associated *List of countries with recognised GMP control system**7 Swissmedic adds foreign manufacturers whose GMP compliance is demonstrated by means of an audit report to a list of candidates for possible inspections carried out by Swissmedic abroad.* |

# Part D: Responsible Person declaration of GMP compliance

The Responsible Person declares the following:

## Responsibilities of the Responsible Person

* The audit report(s) and all the other documentation relating to this declaration of GMP compliance of the manufacturer(s) will be made available for inspection by the competent authorities on request.
* It has been verified that all information concerning the production site in Part A (name, address, activity) is in full agreement with the information contained in the form *Manufacturer information HMV4* as well as in all other relevant parts of the registration dossier.

## GMP compliance

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| The manufacture specified in Part A is in accordance with *(tick as appropriate)*: |
| [ ]  | EU Guide To Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use (EudraLex Volume 4), or PIC/S Guide to Good Manufacturing Practice for Medicinal Products, Part I |
| [ ]  | EU Guide to Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Part II: Basic Requirements for Active Substances used as Starting Materials, or PIC/S Guide to Good Manufacturing Practice for Medicinal Products, Part II |
| [ ]  | Other standards8 (Food GMP, Cosmetics GMP): ……* Based on an audit of the manufacturer and the submitted information (possible exception: veterinary medicinal products, see Part C)
* The outcome of the audit confirms that the manufacture complies with the above-mentioned principles and guidelines of Good Manufacturing Practice.
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| 8 *Only for atypical API. An assessment of the standards together with a risk-based justification must be enclosed* |

## Audit

* In the case of an external audit, the relevant provisions of Chapter 7 of EU-GMP (Outsourced activities) were fulfilled.
* In all cases, the audits were conducted by properly qualified and trained staff in accordance with the recognised procedures.

**Remarks:**

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# Part E: Name and signature of Responsible Person for this declaration

* This declaration is submitted by the Responsible Person of the marketing authorisation holder (see Part B):

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| **The information provided herewith is certified accurate and complete:***(company stamp of the applicant / authorisation holder)*……………… |
| Obligatory | Optional *(additional signature)* |
| Place, date ……Signature ...............................................................Responsible PersonLast name ……First name ……Function ……Phone ……E-mail …… | Place, date ……Signature ...............................................................Additional personLast name ……First name ……Function ……Phone ……E-mail …… |
| **Please send form to:**Swissmedic, Swiss Agency for Therapeutic Products,Hallerstrasse 7, 3012 Berne | **Contact in case of questions:**Telephone +41 58 462 02 11Fax +41 58 462 02 12 |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 2.1 | New layout, no content adjustments to the previous version. | dei |
| 2.0 | Part C: Clarification of which documents must be submitted | hul |
| 1.2 | Formal adjustments to the header and footerNo content adjustments to the previous version. | dei |
| 1.1 | Author in the system synchronised with author in the change history. Release by person in the VM team as the document is not shown in the VMSNo content adjustments to the previous version. | tsj |
| 1.0 | Implementation of TPO4 | dts |